



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Project No. 0803; NRC-2013-0235]

Request to Submit a Two-Part Application – Northwest Medical Isotopes, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to an August 9, 2013, letter from Northwest Medical Isotopes, LLC (NWMI). In this letter, NWMI requested an exemption from certain regulatory requirements, which, if granted, would allow the submittal of a construction permit application for a medical radioisotope production facility in two parts. The NRC staff has reviewed this request and determined that it is appropriate to grant the exemption, as requested.

ADDRESSES: Please refer to Docket ID **NRC-2013-0235** when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this action by the following methods:

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2013-0235**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual(s) listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public](#)

[Documents](#)” and then select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdresource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that the document is referenced.

- **NRC’s PDR:** You may examine and purchase copies of public documents at the NRC’s PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Steven Lynch, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001; telephone: 301-415-1524; e-mail: Steven.Lynch@nrc.gov.

SUPPLEMENTARY INFORMATION:

The following sections include the text of the exemption in its entirety as it will be issued to NWMI.

1.0 Background

Currently, the United States receives all of its supply of molybdenum-99 (Mo-99) from international sources. In recent years, outages at these international facilities have disrupted global supply and created a need to establish domestic Mo-99 production within the United States. In response to this need, NWMI stated in a letter dated August 9, 2013 (ADAMS Accession No. ML13227A295), that it intends to “design and construct a [radioisotope production facility] and intends to produce Mo-99” in order to meet the emerging domestic demands for Mo-99 and its decay product, technetium-99m, in nuclear medicine procedures. Northwest Medical Isotopes, LLC, has proposed to submit an application to construct a

radioisotope production facility pursuant to the requirements of part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), “Domestic Licensing of Production and Utilization Facilities,” and in accordance with 10 CFR 2.101(a)(5) for the purpose of producing Mo-99. As an applicant for a permit to construct such a facility, NWMI will be subject to all applicable rules, regulations, and orders of the NRC now or hereafter in effect.

Generally speaking, production and utilization facility applicants subject to 10 CFR 51.20(b)¹ may submit the information required for a construction permit, under 10 CFR part 50, in two parts, in accordance with the provisions of 10 CFR 2.101(a)(5). These provisions state that one part of the submittal must include the environmental report required by 10 CFR 50.30(f), while the other part must include the preliminary safety analysis report required by 10 CFR 50.34(a). Either part of the construction permit application may be submitted first as long as the submission of each part of the application does not precede or follow the other by longer than six months. However, the first part submitted must also contain the following:

- the description and safety assessment of the site required by 10 CFR 50.34(a)(1),
- the filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21,
- the general information required by 10 CFR 50.33, and
- the agreement limiting access to Classified Information required by 10 CFR 50.37.

Thus, 10 CFR 2.101(a)(5) provides that applicable preliminary safety analysis report information required by 10 CFR 50.34(a)(2) - (a)(13) need not accompany the first part of the submittal. In order to facilitate the review of its application, NWMI would like to submit its application in two parts, as described above; however, based on the current language of 10 CFR 51.20, it cannot

¹ 10 CFR 51.20(b) enumerates the types of licensing and regulatory actions requiring an environmental impact statement or a supplement to an environmental impact statement.

do so unless granted an exemption from certain provisions of 10 CFR 2.101(a)(5) by the Commission.

The NRC staff previously addressed an exemption request from SHINE Medical Technologies, Inc. (SHINE) to submit its construction permit application in two parts. The NRC staff responded to a letter from SHINE, dated July 10, 2012 (ADAMS Accession No. ML12214A434), that asked whether production or utilization facility applicants could submit a construction permit application in two parts even if an environmental impact statement is not explicitly required for the application by 10 CFR 51.20(b).

In a letter dated December 7, 2012 (ADAMS Accession No. ML12319A192), the NRC staff responded:

SHINE's proposed action for licensing a medical isotope production facility is not an action identified in 51.20(b); therefore, 10 CFR 2.101(a)(5) is not applicable to SHINE's licensing proposal. However, SHINE could apply for an exemption under 10 CFR 50.12 in order to submit its application for a construction permit in two parts as described in 10 CFR 2.101(a)(5).

The NRC staff also explained that should an exemption to 10 CFR 2.101(a)(5) be sought, the request must set forth existing special circumstances warranting the exemption, as well as provide the proposed contents of each part of the construction permit application.

Similarly, NWMI has proposed to submit an application requesting the issuance of a construction permit for a medical radioisotope production facility – a licensing action not identified in 10 CFR 51.20(b). Therefore, its application for a construction permit cannot be submitted in two parts under 10 CFR 2.101(a)(5) unless an exemption is granted by the Commission.

2.0 Request/Action

Section 2.101(a)(5) of 10 CFR states, in part:

An applicant for a construction permit under part 50 of this chapter...for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3) or § 50.22 of this chapter...may submit the information required of applicants by part 50...of this chapter in two parts.

By its letter dated August 9, 2013, NWMI requests an exemption from the provision of 10 CFR 2.101(a)(5) that applications for a construction permit under 10 CFR part 50 must be of the type requiring an environmental impact statement or a supplement to an environmental impact statement as described in 10 CFR 51.20(b). The exemption would allow NWMI to submit a portion of its construction permit up to six months prior to the submittal of the remainder of the application regardless of whether an environmental impact statement or a supplement to an environmental impact statement is prepared for its construction permit application. Specifically, in accordance with the provisions of 10 CFR 2.101(a)(5), NWMI proposes to submit the following in part one of its construction permit application:

- the description and safety assessment of the site required by 10 CFR 50.34(a)(1),
- the environmental report required by 10 CFR 50.30(f),
- the filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21,
- the general information required by 10 CFR 50.33, and
- the agreement limiting access to Classified Information required by 10 CFR 50.37.

Part two of NWMI's construction permit application will contain the remainder of the preliminary safety analysis report required by 10 CFR 50.34(a) and 2.101(a)(5). Northwest Medical Isotopes, LLC, has proposed to "design and construct a [radioisotope production facility] and intends to produce Mo-99." In its request for an exemption from certain requirements of 10 CFR 2.101(a)(5), NWMI states that the "demand for medical isotopes is a

significant national public health and safety concern,” and the ability to submit its construction permit application in two parts would “allow for an earlier determination as to whether an [environmental impact statement] is required, allowing a potential earlier completion of the environmental review and ultimate issuance of the Construction Permit...”

3.0 Discussion

To docket NWMI's construction permit application in two parts under 10 CFR 2.101(a)(5), as proposed, an exemption to the regulations is required. Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. While the action requested is not for an exemption to a 10 CFR part 50 regulation, it is appropriate to evaluate this exemption request using the criteria of 10 CFR 50.12 because an application for a construction permit for a radioisotope production facility cannot be accepted for docketing in accordance with 10 CFR 2.101(a) unless it meets the requirements of 10 CFR part 50.

Special Circumstances

The application of 10 CFR 2.101(a)(5) is limited to applications for licensing actions that meet the criteria for environmental impact statements as described in the provisions of 10 CFR 51.20(b) and to facilities of the types specified in 10 CFR 50.21(b)(2) or (b)(3) or 10 CFR 50.22. Northwest Medical Isotopes, LLC, has proposed to submit an application requesting the issuance of a construction permit for a medical radioisotope production facility – a licensing action not identified in 10 CFR 51.20(b). Consequently, its application for a construction permit cannot be submitted in two parts under 10 CFR 2.101(a)(5) unless an exemption is granted by

the Commission. The Commission will not consider granting an exemption under 10 CFR 50.12 unless special circumstances are present. One of the special circumstances listed in 10 CFR 50.12(a)(2) is “(ii) [a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.” Therefore, should the Commission determine that the underlying purpose of 10 CFR 2.101(a)(5) is achieved, application of the regulation would not be necessary, and the special circumstances would exist for granting of an exemption from certain requirements of 10 CFR 2.101(a)(5).

The underlying purpose of the 10 CFR 2.101(a)(5) provision that allows certain applicants to submit an application for a construction permit in two parts is to enable the NRC review of significant portions of the application, as they become available, without unnecessary delay. The provision for two-part construction permit application submittals was added as an amendment to the regulations of 10 CFR part 2, “Agency Rules of Practice and Procedure,” on April 24, 1974 (39 FR 14506). The intent of this final rule was to “reduce the time required to bring on line nuclear power plants which satisfy all environmental and safety requirements...[and remove] unnecessary obstacles to the construction of power plants needed to meet the nation’s energy needs.” Recognizing the procedural nature of the amendment, the Commission made the language of the final rule effective without the customary 30-day notice. It is consistent with the procedural nature of and rationale for the rule to allow NWMI to submit its construction permit application in two parts to facilitate the licensing process of this facility and NWMI’s effort to respond to the nation’s demand for a domestic supply of Mo-99.

Furthermore, when the rule was originally written, there was a “deep national concern over energy sources and supply.” Similarly, there currently exists a national concern over the sources and supply of Mo-99 in the United States. Recognizing this concern, the U.S.

Department of Energy (DOE) and the National Nuclear Security Administration (NNSA) are supporting four separate entities in the development of low enriched uranium technologies to accelerate commercial production of Mo-99 in the United States through the Global Threat Reduction Initiative.² By producing Mo-99 to meet emerging domestic needs, NWMI's proposed medical radioisotope production facility supports the efforts of DOE and NNSA and is in alignment with the underlying purpose of 10 CFR 2.101(a)(5). Therefore, since the underlying purpose of the rule is achieved, application of the regulation is not necessary, and the special circumstances, required by 10 CFR 50.12(a)(2)(ii), exist for granting an exemption from certain requirements of 10 CFR 2.101(a)(5).

Additionally, in 2007, the rule language was modified to include applicants seeking combined licenses under 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (72 FR 49412). The Commission determined that "[t]here are no considerations unique to combined licenses which would weigh against allowing a combined license applicant to submit a two part application under paragraph (a)(5) of § 2.101." Similarly, the NRC staff concludes that given the procedural nature of this rule, there are no unique considerations for medical radioisotope production facilities that would weigh against allowing an applicant such as NWMI to submit a two-part application under 10 CFR 2.101(a)(5).

Authorized by Law

This exemption would allow NWMI to submit its application for a 10 CFR part 50 construction permit in two parts, as provided for in 10 CFR 2.101(a)(5). The exemption would not change the quality or content of the environmental report or the preliminary safety analysis report. The NRC staff has determined that special circumstances exist to support the issuance

² To learn more about the Global Threat Reduction Initiative and U.S. Department of Energy's support of domestic Mo-99 production, please visit <http://nnsa.energy.gov/>.

of an exemption. Thus, the granting of the proposed exemption is consistent with the Atomic Energy Act of 1954, as amended, and the Commission's regulations. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

As described above, the requested exemption is procedural in nature and does not alter any substantive safety requirements regarding the content of a construction permit application. Due to the procedural nature of this request, no new accident precursors are created by allowing an applicant to submit a construction permit application in two parts; thus, the probability of postulated accidents is not increased. Similarly, the consequences of postulated accidents are not increased by an exemption that authorizes an application to be submitted in two parts. Therefore, there is no undue risk³ to public health and safety.

Consistent with Common Defense and Security

As discussed above, the proposed exemption would allow NWMI to submit its application for a 10 CFR part 50 construction permit application in two parts as provided for in 10 CFR 2.101(a)(5). The timing of submitting a construction permit application has no relation to security issues. Therefore, the common defense and security is not impacted by this exemption.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are

³ Risk is defined as the probability of an accident multiplied by the consequences of an accident. More information on risk as it applies to NRC regulatory activities can be found in the Commission White Paper on Risk-Informed and Performance Based Regulation, SECY-98-144 (ADAMS Accession No. ML003753601).

present. Therefore, pursuant to 10 CFR 50.12, the Commission hereby grants NWMI an exemption from the 10 CFR 2.101(a)(5) requirement that limits the regulation's applicability to licensing and regulatory actions requiring environmental impact statements, as described in the provisions of 10 CFR 51.20(b). The exemption granted allows NWMI to submit the construction permit application for its medical radioisotope production facility in two parts, in accordance with the remainder of the provisions of 10 CFR 2.101(a)(5).

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment as it is procedural in nature. Furthermore, the Commission has determined that this exemption request meets the criteria in 10 CFR 51.22(c)(25) for a licensing action that is categorically excluded from the requirement to prepare an environmental assessment because the granting of this exemption: 1) does not involve a significant increase in the probability or consequences of an accident previously evaluated, does not create the possibility of a new or different kind of accident from that previously evaluated, and does not involve a significant reduction in the margin of safety and, thus there is no significant hazards consideration; 2) does not authorize the release of effluents, thus there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; 3) neither authorizes new radiological hazards nor increases existing radiological hazards, thus there is no significant increase in individual or cumulative public or occupational radiation exposure; 4) does not authorize construction, thus there is no significant construction impact; 5) does not authorize any placement of radiological components at a facility or create any new accident precursors, thus there is no significant increase in the potential for or consequences from radiological accidents;

and 6) allows the submission of a construction permit application in two parts, and thus involves a scheduling requirement in accordance with 10 CFR 51.22(c)(25)(vi)(G). This exemption is effective upon issuance to NWMI.

Dated at Rockville, Maryland, this 7th day of October, 2013.

For the Nuclear Regulatory Commission

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